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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/331,204      | 08/20/1999  | ROBERT TAM           | 216/013-US1         | 1379             |

7590 12/18/2002  
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FULLERTON, CA 92835

EXAMINER

SCHULTZ, JAMES

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1635

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/331,204

Applicant(s)

TAM, ROBERT

Examiner

J. Douglas Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 13, 16, 17 and 19-25 is/are rejected.
- 7) ☒ Claim(s) 12, 14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's response filed September 18, 2002 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 16, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Applicant's intention to file a terminal disclaimer to U.S. Patent Number 5,932,556 is noted. The filing of a terminal disclaimer would obviate the double patenting-type rejections of the previous Office action. However, said disclaimer has not been received by the Office as of the writing of this action; thus the rejection of above in regards to claims 1-5, 7-10, 11, 13, and 16 stands until such documentation has been received and acknowledged by the Office.

### ***Response to Arguments***

Claim 6 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the same reasons of record as set forth in the Office action mailed June 18, 2002.

Applicant's amendment of the above claim is noted, but does not obviate the rejection, since, as stated in the previous Office action, this claim as amended still

broadly encompasses any molecule that may potentially come under the grouping of SP1 molecules, such as fragments, homologues from any/all species, splice variants and alleles thereof. Since Applicant's specification does not describe a representative number of SP1 sequences, or domains, motifs, or molecules possessing SP1 function that would constitute written support for such broad language directed to the genus of all SP1 molecules, one of ordinary skill in the art could not properly envision said target as broadly claimed.

Claims 17, and 19-25 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for aptamer-mediated inhibition of SP1 *in vitro*, does not reasonably provide enablement for said inhibition *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the same reasons as set forth in the Office action dated June 18, 2002.

Applicant's amendment, whereby the above claims are now directed to treatment of an immune-competent cell, still encompass *in vivo* applications. Applicant has provided no further arguments to respond to; accordingly, the rejection of the prior Office action is proper.

Claims 1-3, 7, 9, and 10 stand rejected under 35 U.S.C. 102(a) as being anticipated by Patel et al.

Claims 1-6, 8 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sharma et al. or Smith et al.

The invention of the above claims is interpreted as being directed to an aptamer between about 12 to 22 nucleotides wherein at least two G-rich regions exist, said G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG, and GGGn, wherein no directionality of said sequences is indicated. The invention is also drawn to said aptamer where the number of nucleotides separating each of the G-rich regions is 2 to 7, or 3 to 6, or 4, or where one of the at least two G-rich regions comprises GGnG, GnGG, or GGGn, wherein said aptamer competes for the binding site of an immune regulatory protein which may consist of SP1.

As stated in the prior Office action, Patel et al. teach an aptamer in Fig. 1a that is an aptamer having several G-rich regions separated by 6 and 7 nucleotides, which are comprised of GnGG, GGnG, and GGGn. Sharma et al. teach an aptamer wherein the G-rich regions of said aptamer are between 2-7 nucleotides apart and acts on NFκB. Smith et al. teaches G-tetrad oligos wherein each tetrad is separated by four nucleotides.

Applicant traverses the rejections of the prior Office action, reiterated above, on the grounds that the aptamer of Patel et al. does not have a length of between about 12 and 22 nucleic acid units. Further, Applicant argues that none of the cited references

teach the functional limitation of the instant claims, which stipulate that "...the aptamer reduces CD28 expression in an activated human T-cell...."

Arguments regarding the length of the aptamer as taught by Patel et al. are not adopted. Applicant argues that the aptamer of Patel et al. is not between 12 and 22 nucleic acids inclusive, and thus concludes that Patel et al. does not anticipate the present claim. However, it is noted that the claim language only requires the aptamer to be "...between about 12 and 22 nucleic acid units..." Since there is no guidance in the specification as to the definition of "about" in the above claims, the term "about" is given the broadest reasonable interpretation; therefore, the aptamer of Patel et al. is considered to fall within the ambit of Applicant's claim language.

Applicant also argues that although the references listed above teach the claimed structures, they do not specifically teach the claimed function of reducing CD28 expression in an activated human T-cell. However, the structures of the prior art are substantially identical to applicant's claim and are thus considered to possess the functional limitation of reducing CD28 expression in an activated human T-cell in the absence of evidence to the contrary. In rejecting the above claims of under 35 U.S.C. 102 in the prior Office action, a prima facie case was established whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound(s) of the prior art lies with the applicant, as per MPEP 2112.01:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products

of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Also, as per MPEP 2112:

“[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

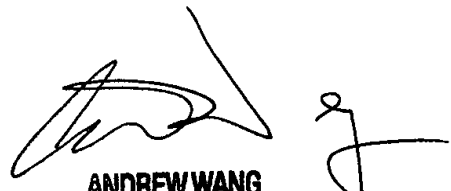
Thus, since Applicant has provided no evidence to rebut the prima facie case established in the prior Office action, and has provided no further arguments supporting the assertion that the prior art does not anticipate the instant claims, the compounds of claims 1-10 of the instant application stand rejected as outlined above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD  
December 17, 2002

  
**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**